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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/944,564	09/04/2001	Nida Abdul-Ghani Nassief		8476

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EXAMINER
LEWIS, PATRICK T

ART UNIT	PAPER NUMBER
1623	5

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/944,564	Applicant(s) NASSIEF, NIDA ABDUL-GHANI	
	Examiner Patrick T. Lewis	Art Unit 1623	

-- The MAILING DATE of this communication appears on the cover she t with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8,14 and 17-24* is/are rejected.

7)☒ Claim(s) *9-13,15 and 16* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Priority

1. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy has been filed herein.

Information Disclosure Statement

2. The disclosure does not contain references listed on a proper information disclosure statement. Therefore, unless the references have been cited by the examiner on form PTO-892, applicant should not assume references have been considered.

Claim Objections

3. Claims 9-13 and 15-16 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only and/or cannot depend from any other multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claims 9-13 and 15-16 have not been further treated on the merits.

Claim Rejections - 35 USC § 101

4. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5. Claims 1, 2, 7, 17, 19, 22, and 24 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1, 5, and 17-24 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of treating allergy/asthma, influenza, and the common cold comprising the administration of glycophosphopeptical, does not reasonably provide enablement for methods for the prophylaxis of allergy/asthma comprising the administration of glycophosphopeptical; methods for the treatment of any disease caused by type I IgE-mediated hypersensitivity reaction comprising the administration of glycophosphopeptical; or methods for the treatment and/or prophylaxis of any viral respiratory tract infection, urinary tract infection, pelvic inflammatory diseases, Crohns disease, facial palsy, or diseases characterized by a body immune defensive mechanism comprising the administration of any Th1 stimulating agents. The specification does not enable any person skilled in the art to

which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Undue experimentation is a conclusion reached by weighing the noted factual considerations set forth below as seen in In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). A conclusion of lack of enablement means that, based on the evidence regarding each of the factors below, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation.

The factors include, but are not limited to:

1. The breadth of the claims,
2. The nature of the invention,
3. The state of the prior art,
4. The level of one of ordinary skill,
5. The level of predictability in the art,
6. The amount of direction provided by the inventor,
7. The existence of working examples, and
8. The quantity of experimentation needed to make and/or use the invention based on the content of the disclosure.

The breadth of the claims

Claim 1 is drawn to the use of glycophosphopeptical for the treatment and/or prophylaxis of allergy/asthma. Claim 5 is drawn to a method of treatment of diseases caused by type I IgE-mediated hypersensitivity reaction comprising the administration of glycophophopeptical. Claims 17 and 19 are drawn to the use of Th1 stimulating agents for the preparation of an agent. Claim 18 is drawn to a method of treatment of viral respiratory tract infections comprising the administration of Th1 stimulating agents. Claim 20 is drawn to a method of treatment of acute and recurrent urinary tract

infection, pelvic inflammatory diseases, and cancer comprising the administration of Th1 stimulating agents. Claim 21 is drawn to a method of treatment of Crohns disease comprising the administration of Th1 stimulating agents. Claim 22 is drawn to the use of Th1 stimulating agent for the treatment of Crohns disease. Claim 23 is drawn to a method of treatment of facial palsy comprising the administration of Th1 stimulating agents. Claim 23 is drawn to a method of treatment of facial palsy comprising the administration of Th1 stimulating agents. Claim 24 is drawn to the use of Th1 stimulating agent for the treatment of facial palsy.

The nature of the invention

The nature of the invention requires a close look at that which is provided in the claims and the scope of the content encompassed by the claim language. The invention is directed to pharmaceutical compositions and methods for the treatment of asthma/allergy comprising the administration of glycocphosphopeptical or pure Nigella sativa seeds. Asthma is a respiratory disorder marked by sudden episodes of coughing, wheezing, shortness of breath, and feelings of suffocation. Glycophosphopeptical is a glucomannan from *Candida tillis* and is known primarily in the art as being used as an immnostimulant for onocology, secondary immunodeficiency, and stimulating cell mediated immunity. Nigella sativa, also know as black cumin, is a well-known herb, and its seeds are widely available for use as a spice or condiment. Nigella sativa has been utilized in folk medicines for treating many diseases including many respiratory symptoms.

The state of the prior art

Sanchez Palacios A. et al. Allergol Immunopathos (Madr), **1992**, Vol 20 (1), pages 35-39 (Sanchez) is seen to be representative of the prior art. Sanchez discloses the use of immunoferon (AM3) in the treatment of childhood infectious respiratory pathology. Sanchez discloses to assess the immunoclinical effectiveness of a biological response immunomodulator, glycophosphopeptide (AM3) was administered to 20 children with asthmatic bronchitis (English Abstract). The children received 2 envelopes (1 g) daily for 4 months. The clinical and immunological parameters assessed were: cough, dyspnea, expectoration, frequency and intensity of the bronchospasm, time of administration of the symptomatic medication, and the delayed cutaneious cells response by means of the intradermal reaction of 5 antigens. Immunoferon reduced the symptoms, the intensity and frequency of the bronchospasm, and the symptomatic medication.

The level of one of ordinary skill

The level of ordinary skill in this art is seen to be that of an M.D. or PhD in the area of medicinal chemistry or a closely related field.

The level of predictability in the art

The prior art teaches that there is no cure for asthma, but it can be treated and managed so that the asthma sufferer can live a normal life. Prevention is best practiced by avoiding allergens, stress, or other irritants that trigger the attack. It is also noted that the examiner has not seen correlations made in the prior art between the treatment of asthma and urinary tract infections, pelvic inflammatory diseases, cancer, or Crohns disease wherein a glucomannan (glycophosphopeptide) is administered as the active

agent. Corticosteroids (steroid) have been shown to be useful for the treatment of a variety of ailments including asthma, Crohns Disease, and cancer; however, corticosteroids are structurally very distinct from glycophosphopeptide. The instant disclosure fails to provide support or rationale for administering glycophosphopeptide for the treatment of medical conditions other than asthma/allergy.

The amount of direction provided by the inventor

The instant specification is not seen to provide adequate guidance which would allow the skilled artisan to extrapolate from the disclosure and examples provided to enable the prophylaxis of asthma/allergy. The specification is not seen to provide support for Th1 stimulating agents other than glycophosphopeptical and purified seeds of Nigella sativa.

The existence of working examples

The working examples in the instant specification are limited to: 1) a double-blind placebo controlled clinical trial involving 120 subjects having seasonal allergic rhinitis, allergic conjunctivitis, chronic urticaria, asthma, and laryngeal edema wherein half of the patients were administered glycophosphopeptical; 2) nine patients with chronic severe asthma were treated according to the present invention administering glycophosphopeptical orally; 3) pulmonary function test; 4) sputum examination; and 5) measurements of Lymphocyte activation and proliferation in culture, after stimulating them by Nigella sativa extracts, comparing it to Purified Protein Derivative (PPD) of Bacillus Calmette Gurene (BCG). There are no working examples drawn to use of Th1 stimulating agents other than glycophosphopeptical and purified seeds of Nigella sativa.

There are no working examples drawn to the treatment of urinary tract infections, pelvic inflammatory diseases, cancer, or Crohns disease.

The quantity of experimentation needed to make and/or use the invention

Indeed, in view of the information set forth supra, the instant disclosure is not seen to be sufficient to enable methods for the prophylaxis of allergy/asthma comprising the administration of glycophosphopeptical; methods for the treatment of any disease caused by type I IgE-mediated hypersensitivity reaction comprising the administration of glycophosphopeptical; or methods for the treatment and/or prophylaxis of any viral respiratory tract infection, urinary tract infection, pelvic inflammatory diseases, Crohns disease, facial palsy, or diseases characterized by a body immune defensive mechanism comprising the administration of any Th1 stimulating agents.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 1-2, 5-8, 14, and 17-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

10. Claims 1-2, 7, 17, 19, 22, and 24 provides for the use of glycophosphopeptical, pure seeds of Nigella sativa, or Th1 stimulating agents, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

11. Regarding claims 1-2, 5, and 17-24, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

12. Regarding claim 4, the phrase "The claim 4 including a dosage regimen" renders the claim indefinite as it is unclear what the phrase is referring to. If applicant intends to limit the composition of claim 4, the claim should be amended to more clearly reflect applicant's intentions.

13. Regarding claim 6, the phrase "preferably" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

14. Regarding claims 1-2, the phrase "allergy/asthma" is not clearly defined. The terms are not seen to be equivalent. If applicant intends for the phrase to be considered in an alternative fashion (i.e. allergy and/or asthma), the claims should be amended to more clearly reflect applicant's intentions.

15. Regarding claims 1-2, 17, and 19, the phrase "treatment and/or prophylaxis" renders the claim indefinite. It is not readily clear from the disclosure as to how treatment **and** prophylaxis are achieved in a single process.

16. The term "pure" in claim 7 is a relative term which renders the claim indefinite. The term "pure" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

17. Claim 8 recites the limitation "pharmaceutical composition as claimed in claim 6" in line 1. There is insufficient antecedent basis for this limitation in the claim.

18. Claim 14 is drawn to the manufacture of a diagnostic kit; however, no active steps are set forth that would apprise one of ordinary skill in the art of the metes and bounds of the claim.

Claim Rejections - 35 USC § 102

19. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

20. Claims 1-8, 17-19, 22, and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Sanchez Palacios A. et al. Allergol Immunopathos (Madr), **1992**, Vol 20 (1), pages 35-39 (Sanchez).

Sanchez discloses the use of immunoferon (AM3) in the treatment of childhood infectious respiratory pathology. Sanchez discloses to assess the immunoclinical effectiveness of a biological response immunomodulator, glycophosphopeptide (AM3) was administered to 20 children with asthmatic bronchitis (English Abstract). The children received 2 envelopes (1 g) daily for 4 months. The clinical and immunological parameters assessed were: cough, dyspnea, expectoration, frequency and intensity of the bronchospasm, time of administration of the symptomatic medication, and the delayed cutaneious cells response by means of the intradermal reaction of 5 antigens.

Immunoferon reduced the symptoms, the intensity and frequency of the bronchospasm, and the symptomatic medication.

Conclusion

21. Claims 1-24 are pending. Claims 1-8, 14, and 17-24 are rejected. Claims 9-13 and 15-16 are objected to as being in improper multiple dependent form and have not been further treated on the merits. No claims are allowed.

Contacts

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick T. Lewis whose telephone number is 703-305-4043. The examiner can normally be reached on M-F 10:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 703-308-4624. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Patrick T. Lewis, PhD
Examiner
Art Unit 1623

James O. Wilson
Supervisory Patent Examiner
Technology Center 1600

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April 15, 2003